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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

BERCH, M

ART UNIT

PAPER NUMBER

1202

DATE MAILED:

07/25/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-17 is/are pending in the application.
- Of the above, claim(s) 6, 7, 11 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-6, 8-10, 12-17 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

BEST AVAILABLE COPY

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Restriction to one of the following inventions is required under
35 U.S.C. 121:

- I. Claim none, drawn to ^rPyrolo~~o~~pyrimidines, classified in class 540,
subclass 280.
- 5 II. Claim none, drawn to purines, classified in class 544, subclass 267,
268, 269, 270, 271, 272, 273, 276, 277.
- III. Claim none, drawn to Imidazo~~o~~pyrimidines, classified in class 544,
546, subclass 18.
- IV. Claims 6-7, 11, drawn to other, classified in class 544, 546,
10 subclass various.

Claim 1-5, 8, 10, 12, 16, 17 link(s) inventions I-III and IV.

Claim 15 link(s) inventions I, II and III.

Claim 9, 12, 14 link(s) inventions I, III and IV.

The inventions are distinct, each from the other because:

15 The groups are distinct as seen by the diversity of the heterocyclic areas
present. Group IV embraces assorted heterocycles such as triazolo pyrimidines,
tetazolo pyrazines, cyclopenta pyndines, imideazopyrimidines, pyazalopyrazines,
etc. Each ^{cl}clearly represents a separate invention as the heterocyclic ring systems

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cannot render each other obvious and can independently support separate utilities.

Because these inventions are distinct for the reasons given above and separate classification restriction for examination purposes as indicated is proper.

During a telephone conversation with Karen DeBenedictis on 7/7/97 a provisional election was made with traverse to prosecute the invention of I, claim 1-5, 8-10, 12-17. Affirmation of this election must be made by applicant in responding to this Office action. Claim 6, 7, 11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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Claims 1-5, 8-10, and 12-17 are rejected as drawn to an improper Markush Group. These do not constitute art recognized equivalents. The claim embrace multiple inventions for reasons set forth above. Narrowing the claim to pyrrolopyrimidines will overcome this rejection.

5 The Abstract objected to. Definitions are needed for A, B, D, E, F, Z and R5.

Claims 1-5, 8-10, 12-14, 16, 17 are rejected under 35 U.S.C. § 112, paragraphs 1 and 2, as the claimed invention is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the
10 ame, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The "wherein" phrase at page 49, lines 16-18 does not make sense. An alkyl group cannot contain multiple bonds of any type. Likewise provision at page 49, lines 19-26; page 50, line 18.

15 2. R2 benzyl in claim 2 is not provided for in claim 1. Note that the list of substituents on ^{C₁-C₁₂} ~~9-92~~ alkyl (starting at page 49 line 30) does not include phenyl³. Since the same claim 1 language appears in the specification as to

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which compounds have the utility, the R2 = benzyl compounds have no ascribed utility.

3. The material beginning at page 49 line 24 ^{had} ~~as~~ no function and should be deleted (through "alkanoyl" on line 28).

5 The R2 list was closed by the "or" on line 20; the "aryl" definition ^{was} ~~was~~ finished at the end of line 23.

4. The inclusion of NR^{1 2}~~R2~~ on page 50, line 5 is clearly ⁱⁿ ~~by~~ error, since it cannot form a "carbonyl ^{cyc} ring". It cannot be rescued by the NZ³ provision because a) this is labeled as "optional" and b) the N-of-attachment cannot be NZ³, as that would give 4 bonds to a ^{neutr} ~~formal~~ N (bond of attachment, 2 for ring, one for Z, which totals 4).

5. The term "^{C1-3} ~~thio~~alkyl" at page 50, line 21 is ambiguous. It could mean a) mercapto ^{C1-3} ~~alkyl~~, e.g. ^{SH C2H4} ~~SH C2H4~~ b) ^{C1-3} ~~alkylthio~~, e.g. ^{C2H5S-} ~~CH3 S-~~.

15 Whichever choice is made must be supported by the specification ^{as} ~~what~~ one skilled in the art would have understood it to be.

6. The "wherein ... bond" of page 51, lines 30-31 ^{fi} ~~ends~~ ^{no a} ~~one~~ antecedent basis in the ^{R5} ~~the~~ definition in claim 1 (and ^{hence} ~~hence~~ is improperly dependent) or in the specification (and hence is ^{not} ~~not~~ enabled).
improperly dependent) or in the specification (and hence is

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7. The language of claims 16-17 is unclear and not enabled. The following issues arise:

a. "such as" is improper alternative language (In re Kingston, 65 USPQ 371)

5 b. "including but not limited to CRF" is of unknown affect. How would ~~the~~^{the} scope of the claim change if this language (or e.g. "including major depression") were removed?

c. The scope of option (a) is unknown and cannot be determined without undue experimentation. To determine that any given disorder (e.g. MS, Type I
10 diabetes) is a disorder which cannot be treated by antagonism^{oni} of CRF would involve essentially open ended research as one tested hundreds of CRF antagonists trying to find out if there is a right one that works. Is there any disorder that applicant can state for certain is not embraced?

d. Some "disorders" are not disorders at all. Pain perception and HIV
15 infections are not disorders (AIDS is a disorder, not HIV infection).

e. What is "psychosocial dwarfism"?

f. Why are both Alzheimer's Disease and SDAT both listed --- These are the same thing?

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g. In addition, applicat^{an}ts have many items which are simply broad categories of only slightly related disorders, e.g. inflammatory disorder, mood disorders, cancer, neurodegenerative disorders, GI diseases, chemical dependencies and addictions, infertility, immune disfunctions, etc. No compound has even been found to be effective against these categories generally - let alone all of them. Thus, there is no compound effective generally against cancer, and given the widely different causes for cancer, there is no reason to think such agent can be found. Similarly, causes vary tremendously for "infertility", and the notion that infertility (in both men and women) generally can be treated is contrary to what is known about infertility, even if some particular types of infertility can be treated. When ^{efforts} ~~effects~~ in the past have ^{failed-} ~~failed~~ and all ^{or} ~~efforts~~ to find a general treatment for e.g. neurodegenerative disorders or cancer have failed --- it is indeed proper to ask for supporting evidence (In re Ferens, 163 USPQ 609). Collectively, the claim is simply in invitation to the public to figure out for themselves which of the hundreds of disorders listed is truly operable.

A scope so broad in effect forces the public to unduly experiment to determine the actual utility. CF In re Schmidt, 153 USPQ 640, which has a

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smaller disclosure than is seen here. Note: Brenner v. Manson, 148 USPQ 693:

"a patent is not a hunting license. It is not a reward for a search, but compensation for its successful completion." The utility here appears to resemble the circumstance in In re Ziegler, 26 USPQ 2d 1600: "... Ziegler was on the way to discovering a practical utility but had no gotten there." Cf also In re Kirk, 153 USPQ 48.

This is futher exacerbated by the enormous scope of Claim 1, which covers ^{ri}illions of compounds.

Any inquiry concerning this communication should be directed to M. Berch at telephone number (703) 308-4718.

M.Berch/vgj
July 23, 1997


MARK L. BERCH
PRIMARY EXAMINER
GROUP 120 - ART UNIT 122